QUOTIENT

Polyspecific Anti-Human Globulin Reagent

BLOOD GROUPING REAGENT

Rabbit Polyclonal / Murine Monoclonal Blend

REF Z350

2°C – 8°C

IVD

CE 1434

INTRODUCTION

This reagent has been prepared by blending rabbit antibodies to human IgG and a murine monoclonal antibody to C3 (class IgG), and pre-diluting the resulting mixture for the optimum detection of IgG and complement binding blood group antibodies by the direct and indirect antiglobulin tests.

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C – 8°C	Storage temperature limitation (2°C– 8°C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer
REF	Product Code

INTENDED PURPOSE

This polyspecific anti-human globulin reagent is for the *in vitro* detection of IgG and complement binding blood group antibodies by the direct and indirect antiglobulin tests.

REAGENT DESCRIPTION

The reagent is a blend of rabbit anti-human IgG and murine monoclonal anti-human C3. The monoclonal antibody to C3 has been given the clone reference number 3G8.
The reagent is diluted in phosphate buffered saline (PBS) which contains 10g/l bovine serum albumin, 1g/l sodium azide and 0.1g/l Tween 80. The reagent is dyed green by the addition of patent blue (0.02g/l) and ariavit tartrazine (0.08g/l). The reagent has been filtered to 0.2µm.
The volume delivered by the reagent dropper bottle is approximately 40µl; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.
This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% sodium azide.
Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide build-up.

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

CAUTION: SOURCE MATERIAL USED IN THE MANUFACTURE OF THIS REAGENT WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN OR ANIMAL BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

This reagent is for *in vitro* professional use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C - 8°C. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

General Information

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- IgG sensitised reagent red cells for control of the antiglobulin test
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES

NIS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass tube.
- Add 1 volume of 2-3% NIS suspended red cells.
- Mix the test well and incubate for 45-60 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0 ± 0.2 (e.g. 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.

- Add two drops of polyspecific anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

Direct Antiglobulin Test

- Add 1 volume of washed (x4) 2-3% NIS suspended red cells.
- Add two drops of polyspecific anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

LISS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass tube.
- Add 2 volumes of 1.5-2% LISS suspended cells.
- Mix the test well and incubate for 15-20 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0 ± 0.2 (e.g. 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.

- Add two drops of polyspecific anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

QUALITY CONTROL

Every batch of antiglobulin tests should include a suitable positive (sensitivity) control, eg R_1r cells sensitised with a weak anti-Rh(D).

PERFORMANCE LIMITATIONS

Washing is best performed with approximately four cycles of 4ml PBS per tube. The use of weak IgG sensitised red cells (e.g. R_1r cells sensitised with anti-Rh(D)) is essential to confirm the activity of an AHG reagent in negative tests. Tests in which negative results are obtained with this procedure should be considered invalid and repeated if necessary.

The inclusion of a green dye in an AHG reagent is not a substitute to the above control test. The presence of the dye serves to indicate that the AHG reagent has been added to a test. The dye does not provide any assurance of the activity of the AHG reagent.

Any PBS present after the completion of the wash phase may dilute the AHG reagent beyond its optimal working concentration. It is therefore important to ensure that the maximum amount of wash fluid is removed after each centrifugation stage.

If automated cell washers are used, the performance and cleanliness of the instrument should be checked frequently.

Direct antiglobulin tests should be performed with fresh cells collected in EDTA anticoagulant to avoid *in vitro* sensitisation with complement. If a positive direct antiglobulin test is observed, specificity can be established by testing with monospecific anti-IgG and anti-C3.

The sensitivity of the reaction of complement with anti-complement reagent can be increased by incubation for 5 minutes at room temperature prior to centrifugation.

Tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

It is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS

Red cells which are direct antiglobulin test positive should not be used in the indirect antiglobulin test.

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For further information or advice please contact your local distributor.

EC REP

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